



DEPARTMENT OF HEALTH & HUMAN SERVICES

93478d

Food and Drug Administration  
Southwest Import District  
Southwest Region  
4040 N. Central Expressway  
Dallas, TX 75204

**WARNING LETTER**

Ref: 2003-SWID-3

April 15, 2003

FEDERAL EXPRESS

Mr. Alejandro Romandia Toyos  
4117 N. 15<sup>th</sup> Ave.  
Apt. 25  
Phoenix, AZ 85015

Dear Mr. Romandia:

On December 20, 2002, your firm imported frozen octopus under entry number AA7-0023033-4. Invoices submitted to FDA listed the product manufacturer as Sociedad Cooperativa de Produccion Pesquera de Altura Y Riberena, Carlos Carillo Redondel (Sociedad Cooperativa). Following an FDA laboratory analysis, the octopus was found to be adulterated with Salmonella and was subsequently refused admission by FDA on February 7, 2003.

On January 30, 2003, you imported a shipment of frozen octopus under entry number AA7-0023635-6 and declared the manufacturer as Sociedad Cooperativa. FDA indicated that this entry appeared to be violative based on the previous Salmonella violation associated with entry AA7-0023033-4. When learning that the product may be detained by FDA, you contacted our investigator and indicated that the entry was actually from a different manufacturer.

When questioned by an FDA investigator, you indicated that your firm commonly buys products from a variety of manufacturers in Mexico and invoices them as if they were manufactured by Sociedad Cooperativa. You also indicated that the product was not actually from or destined for Ocean Garden, although when the entry was examined by an FDA investigator, it was found to have been packed in plastic bags bearing the Ocean Garden brand name. You have provided the information that your firm misrepresents the manufacturers of the products you are importing because Sociedad Cooperativa has all the correct permits with the Mexican government and has not had previous problems with FDA.

You then provided further information regarding the first entry (entry AA7-0023033-4), detained by FDA, stating that it too was not manufactured by Sociedad Cooperativa but was actually manufactured by Productos Congelados Baja Mar, Los Mochis, Sinaloa, Mexico. Fresh frozen octopus from Productos Congelados Baja Mar has been listed on FDA import alert 16-81 since September 2001 and is subject to detention without examination for adulteration with Salmonella.

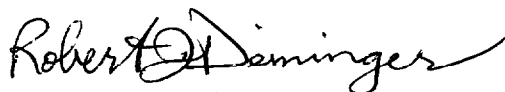
As a result of your misrepresentation of the manufacturer of fresh frozen octopus imported by your firm, we have recommended that the U.S. Customs Service require that future shipments of food imported by your firm be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

Your reply should be addressed to: Rosa Linda Santos, Compliance Officer  
U.S. Food and Drug Administration  
Nogales Port of Entry  
1777 N. Frank Reed Rd.  
Nogales, AZ 85621

Should you have any questions related to this letter, you may also contact Mrs. Santos at 520-281-1100.

Sincerely,



Robert J. Deininger  
Southwest Import District  
District Director